A Participatory Randomized Controlled Trial in Knowledge Translation (KT) to Promote the Adoption of Self-Monitoring of Blood Glucose for Type 2 Diabetes Mellitus Patients in An Urban District of Thailand

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Objective: *To examine effectiveness of self-monitoring of blood glucose (SMBG) in glycemic control for poor control diabetes patients, and test whether the glycemic outcome for those with the 7-point SMBG was better than those with 5-point SMBG or usual care.*
Material and Method: *Randomized-controlled trial (RCT) of patients with type 2 diabetes mellitus aged 30 years or older, HbA1c >7. Patients were randomly allocated to one of three groups; 7-point SMBG, 5-point SBMG and control group. Differences in HbA1c at 6 months and baseline were compared among groups.*
Results: *A total of 191 patients with poor control of diabetes were included. Compared with baseline, at 6 months, average change in HbA1c among control, 7-point, and 5-point SMBG were -0.38, -0.87, and -0.99 (p = 0.04), respectively. The corresponding percentages of patients with reduced HbA1c were 57.1%, 77.6% and 75.5%, respectively (p = 0.03). Using different cut-off values for HbA1c (<7 and <7.5) resulted in different percentage distribution of T2DM patients among the 3 groups, yet the differences were not statistically significant. Reductions in body weight were observed in both SMBG groups but not in the control group.*
Conclusion: *Using RCT on participatory basis, SMBG with individual dietary counseling was effective in short term. Further engagement with the provider team, the patients/care takers and the health care financing agency to integrate SMBG in the care protocol for poor control diabetes should be considered.*

Keywords: *Randomized controlled trial, Self-monitoring blood glucose, Diabetes*

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As early as 2008, Wagner's chronic care model has been adopted and translated into actions nationwide in Thailand using a multi-component approach, i.e., payment mechanism, health professional training (nurse case managers), establishment of administrative dataset and periodic hospital surveys to keep track on pay-for-performance indicators, mobilization of clinical experts in development of clinical practice guidelines for screening and case management, and area-based non-communicable disease (NCD) board to steer the translation processes[1]. Analysis of the administrative dataset revealed increased access to diabetic care from 55% of the prevalence of type 2 diabetes mellitus (T2DM) in 2009 to 96% in 2013[2]. These proportions coincided with the national population-based health examination survey data indicating that the proportions of undiagnosed diabetes decreased from 57% in 2004 to 31% in 2009[3].

The hospital surveys during 2011-2013 demonstrated, corresponding to the analysis, increased access to standard care protocols (pay-for-performance indicators) e.g., annual test for HbA1c, fundoscopy, foot examination, microalbuminuria test, etc[2]. Hospital record data also showed that admission rate of poor

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controlled diabetics or those with its complications has been on the rise since 2005; nonetheless, the rate of amputation of diabetics has declined since 2011[2]. This data might suggest the improvement in access to care, but only in some degree in the care quality or more challenges in self-care motivation.

Although self-monitoring blood glucose (SMBG) formed part of the multicomponent approach, there is no evidence as to the effectiveness of this intervention. A systematic review identified a number of pitfalls of earlier studies on SMBG including lack of information on patient outcomes by treatment received; not providing breakdown of the treatment patients were taking; failure to link SMBG to appropriate education, feedback, treatment and behavior adjustment, as well as an analysis of the types of patients and situations for which SMBG might be most helpful[4].

Mattke et al, 2007 pointed out a need to gain clear and consistent evidence concerning the effects of chronic care management approaches on the population level[5]. In this regard, there are difficulties in design choice: randomized controlled trials (RCTs) lack practicality for evaluating multicomponent, population-based interventions, while most observational designs have severe methodological flaws.

These gaps of knowledge prompted us to respond with combined methods of RCT plus participatory approach of key stakeholders in the design and implementation of SMBG in an urban district hospital situated in an industrial zone of the central region of the country. The hospital is a 150-bed public hospital under the Ministry of Public Health, the biggest health care provider of the country. It provides primary to secondary medical services with ambulatory and inpatient care to a population of 201,444[6]. Annually, it bears a workload of 232,983 ambulatory visits (638 visits/day) and 12,419 inpatient cases with 13 physicians and 95 nurses. In 2011, 30,000 ambulatory visits were classified as endocrine, nutrition and metabolic disease (18% of the total visits which ranked second after circulatory system). For inpatient care, diabetics accounted for 20% of the total admission cases.

Clinical trials showed significant glycemic improvement of T2DM with the structured (7-point) SMBG[7,8] though findings on the cost effectiveness remain controversial[9-12]. Some studies have shown that a 4- to 5-point daily regimen demonstrates an optimal regimen for SMBG in type 1 diabetic patients with acceptable diabetic control. This might be a more efficient option for the glycemic control in T2DM[13]. Therefore, we aimed to test the hypothesis that application of SMBG could improve the glycemic control and whether the glycemic outcome for those with the 7-point SMBG was better than those with 5-point SMBG or usual care.

Material and Method

Participatory processes

Approximately one year prior to the start of a RCT, the investigator teams (1st, 2nd and the corresponding authors) made an informal contact with provincial health officers (the Office Head and the NCD program manager) to explore their concerns and ideas relevant to NCD control in the province. It was found that the officers raised concerns about inadequate care of diabetes and hypertension amidst increasing trends of case load to health facilities which seemed to be out of proportion to the number of health workers. Increased coverage of screening for the conditions was attributed to the trends of case load according to the officers' perception. Current practices of care for diabetics and hypertensives were discussed. In short terms, there was a consensus between the investigators and the officers that improved quality of care for diabetics and hypertensives might be possible, despite the limited number of manpower. The officers felt that improved diabetic care should be at higher priority than that for hypertensive care which was considered less complicated.

Subsequently, several meetings were officially organized between the investigators and diabetic care team (a diabetic mellitus (DM) manager, nurses, internists, general practice doctors, pharmacists and health officers) of a volunteered district hospital including the hospital director. Concept design to improve diabetic care based on SMBG approach was proposed to the diabetic care team and the director for discussion on potential value-added features to the patients, additional workload in terms of data collection, delivery of SMBG as additional intervention to the current practices, and quality assurance processes in the data collection and the delivery of SMBG. It was clear that extra manpower and financial resources were needed to meet the demand for data collection, the delivery of SMBG and the quality assurance. However, mutual understanding was obtained on the need to keep the additional inputs (the data collection, the delivery of SMBG) within a sensible limit to ensure likelihood of future adoption of the upcoming model of care. Then, a subsequent official meeting was held with

the same group of participants to discuss a proposed detailed plan of actions and budget. The detailed plan encompassed type of staff mix, responsibility of each type of staff, patient recruitment and allocation process, time schedule for patient visits, and steps in quality assurance such as calibration of blood sugar test, and supervision of SMBG education.

Prior to actual implementation of the trial, a run-in period was rendered to test the plan so that necessary adjustments could be made such as information sharing among the diabetic care team to ensure that everyone would perform as expected.

Participants

Inclusion criteria for the study were: T2DM patients, 30 years or older, Hemoglobin A1c (HbA1c) >7 and ability to read and write of the subjects and/or care takers. Hospitalized patients during the recruitment period were excluded. The sample size required was calculated based on the estimated difference in fasting plasma glucose (FPG) between SMBG and control of 10, SD of 15 with alpha error of 0.05 and 90% power of test, which gave the number of patients required for each group at 50 cases. A nurse in charge of the diabetic clinic invited each eligible patient to participate until a pool of 200 patients were reached. Then, a research assistant approached each invited patient to give details of the study and ask for informed consent. Baseline data for each patient was obtained using a standard questionnaire, review of medical records and anthropometry assessing smoking status, alcohol use, physical activities, BMI and demographic profile. In addition, urine and blood samples were collected for HbA1c, HDL, LDL, cholesterol, creatinine and urine micro-albumin.

Block randomization with concealment was employed to allocate eligible consenting patients into 3 groups, i.e., intervention group with 7-point SMBG monitoring, intervention group with 5-point SMBG monitoring and control group receiving usual care[14]. The randomization was undertaken by the third author not knowing the baseline data.

Study intervention

Patients or care takers in the 7-point SMBG group were instructed to conduct capillary blood sugar test 7 times a day: before and 2-hour after 3 meals and at bedtime for 2 weekdays and 1 weekend day. These data were used as input for individual diet counseling at a visit in the following week after the test. The counseling was provided by a trained dietitian.

Similarly, those in the 5-point SMBG group followed almost the same activities except that the test was carried out 5 times a day: before and 2-hour after breakfast and dinner, and after lunch.

Patients in the control group received usual care, which was to visit a doctor for medication. Both of the intervention groups also received usual care.

All patients were followed-up on weeks 2, 4, 12 and 24. At the last visit, the same assessments as those at baseline were applied. Review of medical records was carried out to assess percentage of emergency visits, unplanned admission, infection and medications during the follow-up period.

Primary outcome: HbA1c and FPG, emergency visit due to hypoglycemia or hyperglycemia and unplanned admission.

Statistical analysis

All the baseline characteristics were described as mean (SD) for continuous variables and percentage for categorical variables. Difference in mean HbA1c between 6 month and baseline was calculated for each group and compared among groups using analysis of variance. In order to control for baseline HbA1c levels for each group, analysis of covariance was used. Percentage of subjects with reduced HbA1c (HbA1c at 6 months less than HbA1c at start) and percentage of patients with HbA1c <7 and 7.5 at 6 months were calculated and all the percentages were compared using Chi-square test. The p-value of <0.05 was considered statistical significance. All the analyses were performed using SPSS version 11.5.

Results

A total of 191 patients with poor control of diabetes were included, 65, 61, 67 cases in the 7-point SBMG, 5-point SMBG and control group, respectively. Table 1 depicts similar baseline demographic and clinical characteristics of patients with different treatment status except for average age of control group which was 3 to 4 years higher than those of the two treatment groups ($p = 0.043$). There were no significant differences of mean HbA1c among the three arms. At 6 months, HbA1c in all three groups decreased compared with baseline values with higher magnitude in both SMBG groups. The patients with reduced HbA1c were found at a higher percentage in the 2 treatment groups than that of the control (Table 2) ($p = 0.034$). Similarly, on average patients in the treatment groups had bigger reduction of HbA1c than that of the control ($p = 0.042$). Using different cut-off values for HbA1c (<7 and <7.5)

Table 1. Baseline characteristics of patients with different treatment groups

Characteristics	Control (n = 67)	7-point SMBG (n = 65)	5-point SMBG (n = 61)	*p*-value
Male, n (%)	18 (26.9)	21 (32.3)	19 (31.1)	0.773
Smoking, n (%)	7 (10.4)	4 (6.2)	2 (3.3)	0.264
Alcohol drinking, n (%)	4 (6)	10 (15.4)	5 (8.2)	0.168
Regular exercise, n (%)	9 (13.4)	11 (16.9)	10 (16.4)	0.837
Comorbidity: HT and/or DLP, n (%)	65 (97)	63 (96.9)	60 (98.4)	0.852
Age (years), mean (SD)	58.85 (9.26)	54.98 (8.2)	56.64 (8.99)	0.043
Body mass index (kg/m^2), mean (SD)	26.82 (4.16)	26.85 (4.26)	27.89 (5.11)	0.326
Duration of DM (years), mean (SD)	6.25 (4.67)	7.84 (6.25)	7.48 (4.94)	0.203
HbA1c, mean (SD)	8.41 (1.63)	8.72 (1.75)	8.76 (1.9)	0.476
Creatinine (mg/dl), mean (SD)	0.931(0.4)	0.894 (0.51)	0.97 (0.4)	0.623
Urine microalbumin (mcg/gm creatinine), mean (SD)	178.57 (637.36)	174.02 (766.83)	299.73 (698.37)	0.556
Total cholesterol (mg/dl), mean (SD)	191.28 (38.87)	193.08 (32.57)	188.9 (39.03)	0.818
High-density lipoprotein (mg/dl), mean (SD)	47.85 (12.39)	46.12 (10.82)	44.0 (10.96)	0.146
Low-density lipoprotein (mg/dl), mean (SD)	107.42 (35.89)	108.63 (29.24)	104.74 (40.03)	0.820

HT = Hypertension, DLP = Dyslipidemia, DM = Diabetes mellitus

Table 2. Outcome at 6 months of follow-up among control and treatment groups

Outcomes	Control (n = 63)	7-point SMBG (n = 49)	5-point SMBG (n = 49)	*p*-value
Patients (%) with reduced HbA1c at the end of 6 months	57.1	77.6	75.5	0.034
Average HbA1c reduction				
Mean (SD)	-0.38 (1.42)	-0.87 (1.35)	-0.99 (1.32)	0.042
95% CI	-0.74, -0.02	-1.26, -0.48	-1.38, -0.62	
Minimum-maximum	(+3.2) to (-5.6)	(+2.0) to (-6.0)	(+1.7) to (-6.0)	
Emergency visits (%)	1.5	3.1	6.6	0.297
Unplanned admission (%)	6.0	0	3.3	0.141

resulted in different percentage distributions of T2DM patients among the 3 groups, yet the differences were not statistically significant (Table 3).

Compared with baseline, at 6 months, body weight in the treatment groups reduced by 250 grams for the 7 point SMBG group and 559 grams for the 5 point SMBG group (Table 4). In contrast, slight body weight increase (89 grams) was recorded in the control. However, differences in weight changes among the 3 groups did not reach a statistically significant level (p = 0.32). Furthermore, there was no statistically significant difference among the 3 groups in terms of percentage of emergency visits, unplanned admission and infection. Medications for each group of patients were similarly distributed as shown in Table 5 (p>0.05).

Discussion

Using RCT, this study sheds new light on the implementation of SMBG strategy for patients with T2DM, 3 quarters of which were not on insulin. Distinctive interventions employed in our study included dietary counseling on individual patients using SMBG as key feedback to assist the patients in making choices of food and physical activities. Attempts were also made to feed SMBG findings to the physicians on each patient visit yet with varying responses. At the end of 6 months, our study revealed substantial improvement of glycemic control among treatment groups as compared to the control using HbA1c as key indicator (Table 2 and 3). These positive findings corresponded to the finding on weight

reduction as a proxy of compliance to dietary control and physical activity (Table 4). This is in keeping with IDF SMBG guidelines highlighting the combination of meal-based SMBG and comprehensive treatment regimen[15].

Given relatively similar distribution of types of medications among different groups of patients (Table 5), it seems likely that changes in HbA1c and body weight could be a result of dietary control and/or physical activity rather than the effect of medication adjustment during the course of the trial. However, this argument is still uncertain and needs a longer duration of follow-up. Furthermore, the argument may not hold for T2DM patients with lower level of HbA1c (less than 8%).

Apart from testing whether SMBG is effective for T2DM patients with relatively high initial HbA1c (over 8% in our case), the study also aimed at translating this knowledge into practice at an urban district hospital using a participatory approach. The approach started with engagement of the inter-professional team, including the hospital director, as key actors in designing and implementing the study as described in the methods section. The engagement included several formal and informal meetings dealing with situational assessment of diabetic control of the hospital, approaches to fill the gaps accordingly, design of the RCT and implementation plan. Through the engagement, potential obstacles were identified from the beginning, i.e., lack of expertise in delivering SMBG and dietary counseling; lack of staff to handle patient recruitment, data collection and distributing SMBG findings to attending physicians for each patient; and insufficient budget to support HbA1c testing more than once a year. As a result, external resources were mobilized to supplement the perceived deficiency. These included a) recruitment and on-top training of a dietitian to deliver SMBG, dietary counseling, and other functions as mentioned; and b) additional budget for the cost of extra HbA1c testing. These findings are contradictory to the official claim that there exists extra payment for SMBG, monitoring of diabetic complications, and diabetic education by the National Health Security Office, the biggest public health insurance scheme of the country[1]. It highlights a need for better monitoring of hospital performance on delivering SMBG and the reasons for departure from expected performance according to the claimed payment scheme.

During the implementation phase, periodic consultative meetings were held between the researcher team and the inter-professional team to ensure the plan for RCT unfolded as expected. An interesting finding was a strong bond being built between the dietitian on

Table 3. Percentage distribution of T2DM patients by treatment status and HbA1C cut-off values at 6 months

Treatment	At start		At 6th month	
	HbA1c <7 (%)	HbA1c <7.5 (%)	HbA1c <7 (%)	HbA1c <7.5 (%)
Control	16.9	24.6	31.3	37.5
7-point SMBG	10.9	26.6	34.7	55.1
5-point SMBG	13.1	29.5	30.6	19.0
All groups	13.7	26.8	32.1	46.3
p-value	0.606	0.824	0.895	0.16

Table 4. Weight changes at 6 months by treatment status

Treatment	n	Weight changes at 6 months (grams)
Control	65	0.089
7-point SMBG	55	-0.251
5-point SMBG	53	-0.559
All groups	173	-0.217
p-value		0.320

Table 5. Percent distribution of medications for each group of patients

Treatment	n	Medication: n (%)			
		Insulin	Pioglitazone	Metformin	Glipizide
Control	67	17 (25.4)	20 (3.0)	53 (79.1)	54 (80.6)
7-point SMBG	65	18 (27.7)	30 (4.6)	55 (84.6)	48 (73.8)
5-point SMBG	61	16 (26.2)	1 (1.6)	49 (80.3)	54 (88.5)
p-value		0.955	0.628	0.697	0.112

one hand and the nurses and some physicians responsible for diabetic care at the outpatient department on the other hand. This helps explain relatively high compliance of the patients as indicated by small number (17%) of defaulting patients given the fact that keeping patients' appointments depended to a large extent on the nurses' performance.

Successful knowledge translation also depends on acceptability of the patients to intervention. We found higher number of patients in the treatment groups (22.2%) defaulted as compared to that of the control (6%). The reasons for higher default rate in the treatment groups included unacceptable pain in capillary blood sampling, concern for a septic technique during the blood sampling, difficulty in recording of the capillary blood sugar test into SMBG form among elderly patients in particular. Given the growing trend of nuclear families, particularly, in urban area; elderly are likely to live alone either the whole day or during office hours. This fact clearly points out the social context underlying the reasons for the higher default rate. Another reason could be, to a certain extent, related to the demand on the attending physicians to convince the patients about the necessity of SMBG. The expected attempt from the physicians seems to be inadequate given the fact that only 4, including the hospital director, out of the total of 13 physicians participated in designing stages of the trial.

Given those difficulties encountered in our attempts to embed SMBG into the practice, it is arguable that the participatory approach in our study has addressed a major pitfall in KT implementation, i.e., over-reliance on educational strategies without a clear effect on the intended outcomes[16]. Furthermore, our approach addressed the concerns about insufficient detail of the translation processes and the equivocal effects of the interventions.

Concerning further policy decision on scalability of workable SMBG, our findings might be beneficial in terms of availability and acceptance of the current payment system. Despite, the extra payment mechanism introduced in this trial, our findings on the reasons for higher default rate on the patient side raise a need to consider additional payment mechanism or intervention to support care takers of elderly diabetic patients. The reason for low compliance of the physicians is a challenge for strengthening case manager's role in facilitating better alignment of the physician's role which may call for stronger hospital administrative support. Finally, adding a dietitian to the current staff mix to strengthen SMBG implementation might be a necessity, since our findings indicated better achievement in weight reduction among treatment groups as discussed above.

Limitations

There are 3 obvious limitations of our study, i.e., a) the short term assessment of the outcomes rendering skepticism about sustainability of the outcomes, b) scalability of the interventions due to the limited number of hospitals involved, c) lack of cost estimation to justify further financial investment at larger scale. Hence, further studies are needed to recruit larger number of hospitals and subjects with longer term of follow-up plus cost estimation.

Conclusion

This study has demonstrated the feasibility of introducing SMBG for T2DM patients in a district hospital with relatively high burden of outpatient services. Using RCT on a participatory basis, it was evident that care of T2DM patients using SMBG with individual dietary counseling was effective in the short term. This short term success could be a seed to scale up the care protocol through further engagement with the provider team, the patients/care takers and the health care financing agency.

What is already known on this topic ?

A number of pitfalls of earlier studies on SMBG include lack of information on patient outcomes by treatment received; not providing breakdown of the treatment patients were taking; failure to link SMBG to appropriate education, feedback, treatment and behavior adjustment, as well as an analysis of the types of patients and situations for which SMBG might be most helpful.

What this study adds ?

Using RCT on participatory basis (involvement of hospital director and clinicians in the study design and conduct), SMBG with individual dietary counseling is effective in short term for Thailand- a middle income country with universal health coverage.

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Potential conflicts of interest

None.

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ประสิทธิผลของการตรวจน้ำตาลในเลือดด้วยตนเองต่อการคุมระดับน้ำตาลในเลือดของผู้ป่วยเบาหวานในชุมชนเมือง โดยการวิจัยเชิงทดลองแบบมีส่วนร่วม

ไพบูลย์ สุริยะวงศ์ไพศาล, รัศมี ตันศิริสิทธิกุล, ธิดา สกุลพิพัฒน์, พิกุล เจริญสุข, วิชัย เอกพลากร

วัตถุประสงค์: *เพื่อศึกษาประสิทธิผลของการคุมน้ำตาลในเลือดของผู้ป่วยเบาหวานโดยการตรวจติดตามระดับน้ำตาลในเลือดด้วยตนเองของผู้ป่วยเบาหวานที่คุมน้ำตาลในเลือดไม่ดี โดยเปรียบเทียบระหว่างกลุ่มตรวจน้ำตาลโดยเจาะเลือดปลายนิ้ว 7 ครั้ง กลุ่มตรวจ 5 ครั้งต่อวัน และการรักษาแบบทั่วไป*

วัสดุและวิธีการ: *การวิจัยทดลองแบบ randomized-controlled trial ในผู้ป่วยเบาหวานประเภทที่สองอายุ 30 ปีขึ้นไปที่มีระดับ HbA1c >7 แบ่งผู้ป่วยแบบสุ่มเป็น 3 กลุ่มคือ แบบตรวจ 7 ครั้ง, 5 ครั้งต่อวัน และการรักษาแบบทั่วไป (กลุ่มควบคุม) จากนั้นเปรียบเทียบระดับ HbA1c ระหว่างเวลาเริ่มต้นและภายหลังการรักษา 6 เดือน*

ผลการศึกษา: *ผู้ป่วยเบาหวานที่คุมน้ำตาลในเลือดไม่ดี 191 คนเข้าร่วมการศึกษา พบว่าหลังการทดลอง 6 เดือนระดับ HbA1c ในกลุ่มควบคุม กลุ่มตรวจ 7 ครั้ง และกลุ่มตรวจ 5 ครั้ง มีการเปลี่ยนแปลงดังนี้คือ ลดลง 0.38, 0.87 และ 0.99 (p = 0.04) ตามลำดับ สัดส่วนของผู้ที่มีระดับ HbA1c <7 เท่ากับร้อยละ 57.1, 77.6 และ 75.5 (p = 0.03) ตามลำดับ เมื่อกำหนดจุดตัดที่ <7 หรือ 7.5 ผลการเปรียบเทียบไม่เปลี่ยนแปลง นอกจากนี้พบว่าในกลุ่มทดลองตรวจน้ำตาลด้วยตนเองมีดัชนีมวลกายลดลง ส่วนกลุ่มควบคุมไม่ลดลง*

สรุป: *การให้ผู้ป่วยเบาหวานตรวจระดับน้ำตาลด้วยตนเองในระยะสั้น 6 เดือนมีประสิทธิผลในการควบคุมระดับน้ำตาลดีขึ้นระดับหนึ่ง ดังนั้นในผู้ป่วยเบาหวานที่คุมน้ำตาลในเลือดไม่ได้ หน่วยสนับสนุนทรัพยากรควรพิจารณาสนับสนุนการตรวจน้ำตาลในเลือดในผู้ป่วยเบาหวานด้วยตนเอง*